APR 0 8 2003

510(k) Summary of Safety and Effectiveness K030982

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

Device Name and Classification

Product Name:	Syngo Colonography software package
Common Name	3D Reconstruction Software
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.~~1750~~ 2050
Device Class:	Class II
Product Code:	90 ~~JAK~~ LLZ

Establishment:

Importer/Distributor:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Registration Number: 2240869

Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany
***syngo* is a registered trademark of Siemens AG**

Contact Person: Mr. Jamie Yieh
Senior Technical Specialist
Telephone: (610) 448-1785 Fax: (610) 448-1787

Date of Preparation of Summary: November 26th 2002

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

Device Description and Intended Use:

This premarket notification covers Siemens Syngo Colonography software package. It is based on Siemens *syngo* software platform.

syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools

with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-lumenal view), the wall and the outside (extra-lumenal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.
Due to all these capabilities the syngo Colonography software has the advantage of non-invasive evaluation of colonic lesions as compared to conventional colonoscopy.

General Safety and Effectiveness Concerns:
The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.
Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

Substantial Equivalence:
The Syngo Colonography software package, addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
GE CT Colonography/Navigator 2 Workstation	K012313	08/07/01
Siemens Fly Through	K971717	09/03/97
Siemens RealTime 3D Diagnostic Workstation (3D Virtuoso)	K973010	11/10/97

The Syngo Colonography software package described in this 510(k) has the same intended use and similar technical characteristics as the commercially available software listed above.

In addition, many of the image processing, display and evaluation components of syngo Colonography are currently available on software options like the Volume Rendering Technique option, K923524/S2, cleared on May 17th 1994 and workstations like the syngo Multimodality Workstation, K010938 cleared on 26th June 2001 wherein the Fly Thorough software algorithms were transferred over to the syngo software platform. syngo Colonography packages these image processing and image display components in an optimized workflow palette.

In summary, Siemens is of the opinion that Syngo Colonography software package does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 8 2003

Siemens Medical Solutions, Inc.
% Mr. Heinz Joerg Steneberg
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K030982
Trade/Device Name: Syngo Colongraphy Software Package
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 26, 2003
Received: March 28, 2003

Dear Mr. Steneberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for use

510(k) Number (if known): K030982

Device Name: syngo Colonography Software Package

syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools with optimized workflow and reporting tools, the software is designed to support the physician in studying the inside (intra-lumenal view), the wall and the outside (extra-lumenal view) of the colon. With the functionality to view datasets from both the prone and supine positions, it facilitates the detection of colonic lesions (eg. Polyps) in addition to the evaluation, documentation and follow-up of any such lesions using standard spiral CT or MR scanning. This evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the Physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to their size, dimensions, shape and position.
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Concurrence of the CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030982

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)